#### REMARKS

# Specification

The priority statement of the present specification has been amended as suggested by the Examiner. The title of the present application has also been amended to recite the claimed invention as suggested by the Examiner.

#### Claim Objection

Claim 27 is objected to as being of improper dependent form. Applicant submits that claim 27 has been canceled.

## The 35 USC §112 Rejections

Claims 26-31 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection is respectfully traversed.

Claims 26-31 stand rejected for reciting "producing immune-activated cells" and "exposing dendritic cells" in claim 26. Applicant submits that claim 26 has been amended to recite a method of producing activated T cells directed toward stratum corneum chymotrytic enzyme (SCCE), comprising the steps of exposing dendritic cells to SCCE polypeptides to produce activated

dendritic cells, and then exposing said activated dendritic cells to T : cells to generate SCCE-reactive T cells.

Claim 27 is rejected for reciting "dendrites". Applicant submits that claim 27 has been canceled.

Applicant submits that the claims as amended have particularly pointed out and distinctly claimed the subject matter of the present invention. Accordingly, Applicant respectfully requests that the rejection of claims 26-31 under 35 U.S.C. §112, second paragraph, be withdrawn.

Claims 26-31 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with written description requirement. The Examiner contends that the specification does not reasonably provide written description for a method of producing immune-activated cells directed towards any stratum corneum chymotrytic enzyme comprising the step of exposing dendritic cells to any stratum corneum chymotrytic enzyme or any fragment thereof.

Applicant submits that claim 26 has been amended to recite a method of using polypeptides of stratum corneum chymotrytic enzyme (SCCE) to produce SCCE-reactive T cells, wherein said SCCE polypeptides include those with amino acid

sequences of SEQ ID Nos. 31, 32, 33, 34, 35, 36, 80, 86, 99, and polypeptide encoded by the DNA of SEQ ID NO.30. Applicant submits that the specification has provided adequate written description and evidence of possession for the recited SCCE polypeptides as shown in the disclosed sequences of SEQ ID Nos. 30, 31, 32, 33, 34, 35, 36, 80, 86 and 99. Accordingly, Applicant respectfully requests that the rejection of claims 26-31 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claims 26-31 are rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner contends that the specification, while being enabling for a method of using fragments of stratum corneum chymotrytic enzyme (SCCE) with the sequences of SEQ ID Nos. 31, 32, 33, 34, 35, 36, 80, 86 and 99 to produce SCCE-reactive T cells, does not reasonably provide enablement for a method of producing immune-activated cells directed towards any stratum corneum chymotrytic enzyme comprising the step of exposing dendritic cells to any stratum corneum chymotrytic enzyme or any fragment thereof.

Applicant submits that claim 26 has been amended to recite a method of using polypeptides of stratum corneum chymotrytic enzyme (SCCE) to produce SCCE-reactive T cells,

wherein said SCCE polypeptides include those with amino acid, sequences of SEQ ID Nos. 31, 32, 33, 34, 35, 36, 80, 86, 99, and polypeptide encoded by the DNA of SEQ ID NO.30. Dendritic cells are first exposed to SCCE polypeptides to produce activated dendritic cells, which are then used to stimulate T cells to generate SCCE-reactive T cells. The methodology of using peptide-pulsed dendritic cells to generate immune-activated T cells is readily. available to one of ordinary skill in the art, and in view of the SCCE polypeptides disclosed herein, one of ordinary skill in the art could practice the claimed invention without undue experimentation. Applicant submits that the scope of the claimed invention is commensurate with the scope of enablement provided in the specification. Accordingly, Applicant respectfully requests that the rejection of claims 26-31 under 35 U.S.C. §112, first paragraph, be withdrawn.

### The 35 USC §103 Rejection

Claims 26-31 are rejected under 35 USC §103(a) as being unpatentable over **Paglia** et al. (1996) in view of **Cohen** et al. (U.S. Patent 6,232,456). This rejection is respectfully traversed.

The present invention is drawn to a method of using polypeptides of stratum corneum chymotrytic enzyme (SCCE) to produce SCCE-reactive T cells, wherein said stratum corneum chymotrytic enzyme polypeptides include those with amino acid sequences of SEQ ID Nos. 31, 32, 33, 34, 35, 36, 80, 86, 99, and polypeptide encoded by the DNA of SEQ ID NO.30. Dendritic cells are first exposed to stratum corneum chymotrytic enzyme polypeptides to produce activated dendritic cells, which are then used to stimulate T cells to generate stratum corneum chymotrytic enzyme-reactive T cells.

In contrast, **Paglia** et al. teach priming of immune response against a major histocompatibility complex class I-restricted antigen by utilizing dendritic cells for presentation of tumor-associated antigens. **Paglia** et al. do not teach a method of using dendritic cells loaded with stratum corneum chymotrytic enzyme peptides to produce activated T cells directed toward stratum corneum chymotrytic enzyme. The Examiner contends, however, this deficiency is made up for by **Cohen** et al. that teach a serine protease (SEQ ID NO.33) comprising SEQ ID NOs. 31, 32, 34, 80 and 99 of the present invention. Applicant respectfully disagrees.

Applicant submits that **Cohen** et al. do not teach the same stratum corneum chymotrytic enzyme polypeptides as disclosed herein. SEO ID NO.33 disclosed in Cohen et al. is a protein of 224 amino acids, whereas the present invention recites the use of full length stratum corneum chymotrytic enzyme polypeptide or stratum corneum chymotrytic enzyme peptides that are 9 amino acids in length. Cohen et al. do not teach or suggest using 9 amino acids-long peptides, let alone a method of using SEQ ID Nos. 31, 32, 33, 34, 35, 36, 80, 86 and 99 as disclosed herein. Hence, combining Paglia et al. and Cohen et al. would not lead one of ordinary skill in the art to the present invention. The invention as a whole is not *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Accordingly, Applicant respectfully requests that the rejection of claims 26-31 under 35 U.S.C. §103(a) be withdrawn.

# Obviousness-Type Double Patenting Rejection

Claims 26-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-11 of copending Application No.

10/372,521. Applicant hereby submits a terminal disclaimer to obviate the provisional rejection.

Applicant further submits that the instant application and copending Application No. 10/372,521 are commonly owned and subject to an obligation of assignment to the same person at the time the later invention was made.

This is intended to be a complete response to the Office. Action mailed March 25, 2004. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: /ugust 25, rooy

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